ANGEION CORP/MN
Form 10-K
January 29, 2008

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 for the fiscal year ended October 31, 2007.**

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 for the transition period from to .**

Commission File Number 001-13543

ANGEION CORPORATION

(Exact name of registrant as specified in its charter)

Minnesota	**41-1579150**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

350 Oak Grove Parkway, Saint Paul, Minnesota 55127-8599

(Address of principal executive offices)

Registrant s telephone number, including area code: (**651) 484-4874**

Securities registered pursuant to Section 12(b) of the Act: Securities registered pursuant to Section 12(g) of the Act: **None**

Common Stock, $0.10 Par Value

Name of Exchange on Which Registered: NASDAQ

Indicate by check mark whether the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act:

Yes o No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act:

Yes o No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes x No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act:

Large Accelerated Filer o Accelerated Filer o Non-Accelerated Filer x

The aggregate value of the Company s Common Stock held by non-affiliates of the Company was approximately $31,987,000as of the last day of the Company s most recently completed fiscal quarter, when the last reported sales price was $7.86 per share.

As of January 24, 2008, the Company had outstanding 4,089,803 shares of Common Stock, $0.10 par value.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information is incorporated into Part III of this report by reference to the Proxy Statement for the Registrant s 2008 Annual Meeting of Shareholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

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PART I

Item 1. Business.

Unless the context requires otherwise, references in this Form 10-K to Angeion or the Company means Angeion Corporation, while references to Medical Graphics refer to Medical Graphics Corporation, a wholly owned subsidiary of Angeion. Angeion and Medical Graphics are collectively referred to as the Company.

(a) General Development of Business.

Events Prior to 2000

Angeion Corporation was incorporated in Minnesota during May 1986 for the purpose of developing, manufacturing and selling medical products. In July 1988, Angeion merged with Verde Ventures Incorporated, a public company organized in March 1987 that had no operations at the time of the merger and the surviving legal entity changed its name to Angeion Corporation.

During the period from 1990 through March 2000, Angeion was engaged in the development and sale, directly and through joint ventures, of automatic implantable cardioverter defibrillator (ICD) systems. ICDs are designed to treat abnormally rapid heartbeats in the ventricular (or lower) chambers of the heart, a condition known as ventricular tachycardia (VT), and a severe form of VT known as ventricular fibrillation (VF), that if not terminated will lead to sudden cardiac death. ICDs are electronic devices that are implanted within the body and are connected to the heart with defibrillator leads. These devices monitor the patient s heartbeat and, in the event of VT or VF, deliver an electrical shock to return the heartbeat to normal rhythm. During 1999 and 2000, the Company completed two restructurings, granted a series of non-exclusive licenses to its ICD technology and discontinued its ICD operations.

In December 1999, Angeion acquired Medical Graphics Corporation.

Subsequent Developments.

- In March 2000, Angeion acquired the operating assets of AeroSport, Inc., a privately-held Ann Arbor, Michigan corporation, and obtained an exclusive worldwide license to AeroSport s patented technology for gas exchange metabolic analyzers for the health, fitness, and research and education markets.
- During 2001, Angeion introduced the New Leaf brand as the umbrella brand name for its planned family of health and fitness products to be marketed to consumers through health and fitness clubs, cardiac rehabilitation centers, weight loss centers and other retail outlets.
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On June 17, 2002, Angeion filed a voluntary petition for reorganization under Chapter 11 of the federal bankruptcy laws (Chapter 11 or Bankruptcy Case) in the United States Bankruptcy Court for the District of Minnesota and in the process converted $20.0 million of Convertible Notes into 95% of the Company s common stock. Angeion emerged from Bankruptcy in October 2002.

- In June 2002, Angeion received a notification that some of the ICDs formerly manufactured by it were experiencing premature battery depletion. Angeion advised the attending physicians of the patients with these ICDs of the problems associated with these ICDs and provided a recommended

protocol. During fiscal 2005, Angeion resolved all matters relating to indemnification by Angeion of its former joint venture partner in the manufacture and distribution of ICDs and, during fiscal 2006, Angeion resolved all issues related to its insurance coverage in this matter. Angeion incurred a loss from discontinued operation of $229,000 in fiscal 2005 and a gain of $171,000 from discontinued operation in fiscal 2006 related to its former ICD operations.

(b) Financial Information about Industry Segments.

The Company is a medical device manufacturer that designs and markets non-invasive cardiorespiratory diagnostic systems. All of the Company s cardiorespiratory diagnostic products are similar because they have a common functional testing platform the measurement of air flow and respiratory pressures and, in most cases, the analysis of inhaled and exhaled gases such as oxygen and carbon dioxide. Consequently, the Company operates in a single industry segment: the research, development, manufacture and marketing of medical devices and fitness related products, including non-invasive cardiorespiratory diagnostic systems.

(c) Narrative Description of Business.

General

Through its Medical Graphics Corporation subsidiary, Angeion designs and markets non-invasive cardiorespiratory diagnostic systems that are sold under the MedGraphics and New Leaf brand and trade names. These cardiorespiratory diagnostic systems have a wide range of applications in healthcare, wellness, and health and fitness.

Healthcare professionals use these cardiorespiratory diagnostic systems to diagnose shortness of breath and lung diseases such as asthma and emphysema, and manage related treatment. Through breath-by-breath analysis, some of the Company s cardiorespiratory diagnostic systems measure fitness or conditioning levels to help physicians diagnose heart diseases such as heart failure and coronary disease. The Company sells its cardiorespiratory diagnostic systems and services to clinical research customers for use in conducting safety and efficacy clinical trial studies both in the United States and internationally. Other health professionals use cardiorespiratory diagnostic systems to measure calorie consumption and to prescribe safe and effective exercise in rehabilitation, weight management, general fitness, and athletic performance. All of these applications are accomplished by measuring air flow and the concentrations of inhaled and exhaled gases such as oxygen and carbon dioxide while a person is at rest, or exercising on a bike or treadmill. Professionals use this same assessment of gases and air flow to determine nutritional requirements of critically ill patients in a hospital or to design a weight loss program for members in a health club wishing to assess the number of calories they should consume and burn daily.

Primary MedGraphics brand products include pulmonary function (PFT) and cardiopulmonary gas exchange (GX) testing systems. All MedGraphics systems are designed to be simple and easy-to-use while at the same time provide the flexibility to address the specific needs of hospitals, clinics and physician offices. All MedGraphics products, except for certain OEM products, are sold with a personal computer, full color monitor, printer and other peripherals.

The Company also sells one of its cardiorespiratory diagnostic systems together with other consumable products under the New Leaf brand to consumers through health and fitness clubs, personal training studios, weight loss centers and other retail outlets. These fitness products provide the consumer with a personalized exercise plan based on an assessment of the individual s level of fitness and metabolism. The assessment is performed at a health club or personal training studio equipped with one of the Company s VO2 assessment systems. Through the New Leaf assessment, an individual s

metabolism is measured and correlated to the heart rate while exercising. The participating consumer must purchase an assessment package containing the single user materials required for the VO2 assessment and, optionally, a heart rate monitor and watch to help the user exercise at the correct intensity level to achieve the desired results for weight loss, general fitness improvement or athletic performance.

Pulmonary Function Systems

Health care professionals use assessment of pulmonary function to diagnose lung diseases such as asthma and emphysema, and manage treatment of their patients. Pulmonary function applications include screening asthma patients, pre-operative and post-operative assessment of heart and lung surgery patients, evaluating lung damage from occupational exposures and documenting responses to therapy.

These pulmonary function systems fall into three major product categories: Spirometry, Complete Pulmonary Function and Body Plethysmography.

Spirometry. The CPF-S/D USB spirometer is comprised of a flow measurement module and a personal computer (PC). The spirometer can serve as a platform that can be upgraded to either a complete pulmonary function or cardiopulmonary exercise system. Spirometry provides measurements of airflow, lung volume and elastic/mechanical properties.

Complete Pulmonary Function Systems. The Ultima/PF Series is MedGraphics complete pulmonary function system. The Ultima/PF is available as a desktop or cart-mounted module that performs rapid, non-invasive assessment of an individual s lung volumes, respiratory pressures and gas diffusion in addition to spirometry measurements. The Ultima PF uses a patented patient circuit to enhance infection control.

Body Plethysmograph Systems. The Elite Series comprises MedGraphics body plethysmograph system. A body plethysmograph is an enclosed metal and clear acrylic chamber that offers the most sensitive method for measuring chest wall movement. The patient sits inside the chamber and undergoes diagnostic pulmonary function tests. MedGraphics medical design award winning Elite Series minimizes patient anxiety and discomfort while maximizing accuracy. The system s design optimizes patient comfort with a clear-view acrylic enclosure and allows testing of a broad population including pediatric patients and individuals in wheelchairs.

The Elite Series is available in three configurations:

Elite D. The Elite D performs spirometry, measures the total volume of air in the lungs and the resistance to airflow in the airways of a person s lungs.

Elite DL. The Elite DL performs the same tests as the Elite D, and adds the diffusion test in the same manner as the Ultima/PF.

Elite DX. The Elite DX performs all the same tests as an Elite DL, and adds an additional lung volume measurement.

All MedGraphics pulmonary function products use the patented preVent™ pneumotach, a disposable/cleanable mouthpiece/flow measurement device that eliminates concern over the transmission of infectious diseases. The preVent pneumotach gives all MedGraphics products the capability to perform spirometry testing to measure the flow rates, volumes (capacities) and mechanical properties of the lung. MedGraphics pulmonary function products use a patented expert system, Pulmonary Consult, to assist physicians in the interpretation of test results.

Applications include evaluating the effect of medication, monitoring patients with chronic disease, diagnosing lung diseases (i.e. asthma and emphysema), managing treatment, assessing the surgical risk of lung transplant and lung reduction candidates and evaluating the impact of diseases such as neuromuscular disease on breathing.

MedGraphics pulmonary function products ease of use, infection control features, compact, lightweight design and mobility option attract a wide variety of customers, including pulmonary laboratories in hospitals, clinics, physician offices, occupational medicine clinics, asthma/allergy practices, and clinical research centers worldwide.

Cardiopulmonary Exercise Testing Systems

MedGraphics cardiopulmonary exercise (CPX) testing systems measure functional capacity, fitness or conditioning levels as well as help physicians diagnose heart and lung diseases. This is accomplished by measuring the volume and concentrations of oxygen and carbon dioxide as they enter and leave the lungs while a person exercises on a machine such as a bike or treadmill.

The Ultima/CPX systems measure each breath using a patented breath-by-breath methodology and the same patented preVent pneumotach as the pulmonary function systems. MedGraphics cardiopulmonary exercise systems include a patented oxygen analyzer and a carbon dioxide analyzer as well as patented gas sampling and data reporting, including an evaluation of the information obtained from cardiopulmonary exercise assessments.

Measurements can also be made at rest to determine nutritional requirements of critically ill patients or individuals wishing to assess the number of calories burned per day, which is termed energy expenditure. This measurement is known as a metabolic assessment and is marketed by Medical Graphics as the Ultima/CCM option. Configurations using both the CPX and CCM applications are marked as an Ultima/MAX system.

The Ultima Series is sold in the following different configurations**:**

Ultima/CPX/D. This is a basic exercise testing system that measures an individual s fitness level while exercising and measures the ability to perform work (functional capacity) or activities of daily living. The Ultima/CPX/D can also be used in conjunction with other manufacturers stand-alone ECG systems. The electrocardiogram, which measures heart functions, is generally referred to as an ECG.

Ultima/CCM/D. This basic metabolic assessment system measures the nutritional requirements of a patient at rest.

Ultima/CardiO$_2$. This configuration adds an integrated 12-lead electrocardiogram stress option.

VO2000. The VO2000 is a portable/ambulatory version that is about twice the size of a typical portable CD player and can transmit data via telemetry. In addition to uses for exercise and nutritional requirements, these portable and wearable products include assessment of work capacity in occupational medicine and physical therapy as well as field training of amateur and elite athletes during participation in their actual events. The VO2000 technology platform, reconfigured as a VO2PAS, is a key component of the Company s New Leaf Active Metabolic Training™ System health and fitness product.

Applications for the Ultima and VO2000 exercise and metabolic systems include distinguishing between cardiovascular and pulmonary disease, screening for early signs of cardiac and pulmonary dysfunction, establishing exercise prescriptions and training programs and evaluating the efficacy of prescribed therapy. Customers include hospital cardiopulmonary laboratories, cardiology and pulmonary office-based clinics, critical care units, cardiac rehabilitation units, weight loss clinics, human performance laboratories and health clubs.

Cycle Ergometers and Treadmills

The Company offers several models of cycle ergometers providing healthcare professionals and patients a tool for more successful outcomes in clinical rehabilitation and athletic training. A cycle ergometer is a specially designed stationary exercise bicycle that can operate at a broad spectrum of resistance levels while a treadmill is a motorized walking/running surface that can operate at different inclines to produce a range of work levels. Medical Graphics has cycle ergometers and treadmills that are used in diagnostic, rehabilitation, training and sports medicine applications. The ergometers and treadmills are used and controlled by the Company s cardiopulmonary exercise testing systems.

Competition

The industry for companies selling cardiopulmonary diagnostic systems is competitive. There are a number of companies that currently offer, or are in the process of developing, products that compete with products offered by Medical Graphics. The Company s competitors include both large and small medical companies, some of which have greater financial and technical resources and broader product lines. Viasys Healthcare, Inc., which was acquired by Cardinal Health, Inc in June 2007 and nSpire Health are the principal competitors for the Company s MedGraphics branded products. The Company believes that the primary competitive factors in its markets are product features, customer service, price, quality, product performance, market reputation, breadth of product offerings and effectiveness of sales and marketing efforts. The Company believes its MedGraphics brand product quality, product performance, market reputation and customer service are the true differentiators that will contribute to future growth.

The Company s New Leaf branded products for the health and fitness market have a few competitors, which include metabolic measurement systems (Korr Medical and Cosmed), nutrition education and lifestyle enhancement software (e-Diets) and weight loss programs (Jenny Craig and Weight Watchers). The Company believes that its proprietary technology, expert-designed exercise programs and its training and education service provide a notable and unique advantage in the weight loss, general fitness and athletic performance markets.

The Company believes competition based on price will continue to be an important factor in customer purchasing patterns as a result of healthcare cost containment pressures in the health care industry. Price competition may exert downward pressure on prices the Company is able to charge for its products. There can be no assurance that it will be able to offset any downward price pressure through corresponding cost reductions. Any failure to offset this pressure could have an adverse effect on the Company s business, results of operations or financial condition.

Any product developed by the Company that gains regulatory approval will have to compete for market acceptance and market share. The timing of market introduction of competitive products could adversely affect the competitiveness of Medical Graphics products. Accordingly, the relative speeds with which the Company can develop products, complete clinical testing and the regulatory approval process and supply commercial quantities of the product to the market are important competitive factors. The Company expects that competition will also be based on many factors, including device size and

weight, longevity, ease of programmability, ability to provide diagnostic capability, product reliability, physician familiarity with the device, patent protection, sales and marketing capability, third-party reimbursement policies, reputation and price. The Company has protected its products with various patents when possible.

Manufacturing

Medical Graphics currently designs and assembles all major analyzer components of its cardiopulmonary diagnostic systems including a waveform analyzer, flow board, gas sample lines, gas chromatograph, nitrogen analyzer, CO2 analyzer and oxygen analyzer. Company-designed sheet metal, electrical components, printed circuit boards and some measurement devices are purchased from outside vendors and are tested, assembled and packaged by Medical Graphics personnel into fully integrated systems. Medical Graphics also acquires general-purpose computers, monitors and printers from a variety of sources and integrates its proprietary software modules into these systems. Medical Graphics acquires its cycle ergometers and treadmills from third parties.

Medical Graphics Quality Management System is certified to the requirements of ISO 13485:2003, Canadian Medical Device Regulations Part 1, and European Union Medical Device Directive Annex II regarding the Development and Production of Cardio Respiratory devices. See Regulation by Foreign Governments for additional discussion of the Company s ISO 13485:2003 certification.

Marketing and Distribution

Medical Graphics markets its products in the United States through two direct sales forces that sell into hospitals, university-based medical centers, medical clinics, physician offices, health and fitness clubs, weight loss clinics and personal training studios. The Company markets its products to a wide range of customers that utilize its non-invasive capabilities across a broad healthcare market continuum. On the healthcare end of the continuum, the MedGraphics branded products are sold to hospitals, physician offices, clinics, pulmonary physicians, cardiologists, critical care physicians, rehabilitation professionals and physical therapy professionals. On the fitness end of the continuum, the New Leaf branded products are sold to health and fitness clubs, corporations, weight loss centers, training studios, personal trainers and coaches. Each salesperson is responsible for a specific geographic area and is compensated with a base salary, expense reimbursement and a territory sales goal commission plan.

Outside the United States, Medical Graphics markets its products through a network of independent distributors. During 2007, Medical Graphics used approximately 56 distributors to sell its products into 70 countries. These distributors typically carry a select inventory of MedGraphics products and sell those products in specific geographic areas, generally on an exclusive basis. International revenues accounted for 24.8%, 29.7% and 16.5% of total revenue for the years ended October 31, 2007, 2006 and 2005, respectively. All of Medical Graphics international sales are made on a United States dollar-denominated basis to distributors.

International sales involve certain risks not ordinarily associated with domestic business including fluctuations in currency exchange rates, reliance on distributors and country-specific policies and procedures.

Medical Graphics executes multiple sales and marketing strategies both domestically and internationally. The Company s most successful sales and marketing tactics include product demonstrations which emphasize technological capabilities, breadth of services and unmatched customer

service. In addition to onsite product demonstrations, the Company annually attends and hosts booth

displays at various industry-specific conventions around the world. At these conventions, potential customers/clients have the ability to see and experience the unique features the products offer. Through these global conventions, the Company gains exposure to pulmonologists, respiratory therapists, allergy physicians, exercise physiologists, sports medicine professionals, personal trainers and exercise enthusiasts. Other marketing initiatives include educational seminars, print advertisements, direct mail campaigns and e-marketing campaigns through the (www.medgraphics.com) web site for MedGraphics branded products and (www.newleaffitness.com) for New Leaf branded products.

Research and Development

In 2007, Medical Graphics continued to develop new products and implemented product improvements designed to enhance product reliability and improve margins. The Company s research and development initiatives are targeted for hospitals, clinics, physician s offices and the health and fitness club markets. An integral component of the Company s future growth strategies includes developing and introducing additional new products.

Research and development expenses were $2.8 million, $2.4 million and $2.1 million for the years ended October 31, 2007, 2006 and 2005, respectively.

Intellectual Property

Patents and trademarks are critical in the medical device industry. The Company believes strongly in protecting its intellectual property and has a long history of obtaining patents, when available, in connection with its research and product development programs. The Company also relies upon trade secrets and proprietary know-how.

The Company relies on a combination of patent, trademark and trade secret laws to establish proprietary rights in its products. Medical Graphics currently owns 24 United States patents and is actively developing and obtaining additional patents. These patents cover the various aspects of Medical Graphics core technologies, including gas analysis, pressure and flow measurement, breath-by-breath assessment of gas exchange data analysis and expert system software. The New Leaf products employ various Medical Graphics patents in its business model. In addition, Medical Graphics has a number of foreign patents with respect to technologies covered by its United States patents.

Prior to June 2005, the Company owned a number of cardiac stimulation patents. These patents were assigned to ELA Medical in connection with settlement of the legal dispute by ELA Medical against the Company.

Foreign patents generally expire 20 years after the date of original application, but vary from country to country. Medical Graphics intends to aggressively enforce its intellectual property rights and has successfully done so in the past. There can be no assurance, however, that these patents, or any patents that may be issued as a result of existing or future applications, will offer any degree of protection from competitors.

United States patents filed on or after June 8, 1995 have a term of 20 years from the date on which the application for the patent was filed. Domestic patents in force on June 8, 1995 and patents issued on applications filed prior to June 8, 1995 automatically have a term that is the

greater of the 20 years from the date of filing or 17 years from the patent grant.

Medical Graphics also owns registered trademarks and has applied for other trademarks in the U.S. and certain foreign countries. Medical Graphics owns and actively enforces an array of related

copyrights and trademarks. These include but are not limited to: MedGraphics, preVent Pneumotach, BreathPath, BreezeSuite, CPX/D, CCM/D, CardiO2, CPX/Express, CCM/Express, Ultima/PF, Ultima/CPX, Ultima/CCM, Ultima/PFX, 1085/DX, Elite/Dx, Elite/DL, PF/Dx, Profiler/Dx, Profiler/DL, CPF-S/D, Pulmonary Consult, Exercise Consult, KnowledgeNet and various logos.

Similarly, Medical Graphics owns New Leaf trademarks and copyrights that include but are not limited to: New Leaf, ExerSmart, ExerScript, PDC Personal Digital Coach, PAS Personal Assessment System, New Leaf Active Metabolic Training, EnerySmart and various logos.

Although patent and intellectual property disputes in the medical device area have often been settled through licensing agreements or similar arrangements, costs associated with these arrangements may be substantial, and there can be no assurance that necessary licenses would be available to the Company on satisfactory terms, if at all. Accordingly, an adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent the Company from manufacturing and selling its products, which would have a material adverse effect on the Company s business, financial condition and results of operations.

The Company seeks to protect its trade secrets and proprietary know-how, in part, through confidentiality agreements, non-compete agreements and assignment of invention provisions in agreements with employees, consultants and other parties, as well as through contractual exclusivity with certain suppliers. There can be no assurance, however, that these agreements will not be breached, that the Company would have adequate remedies for any breach, or that the Company s trade secrets will not otherwise become known to or independently developed by competitors.

The Company conducts ongoing evaluations of potential infringement of any proprietary rights of third parties by the products the Company intends to market. Regardless of the Company s efforts to evaluate the potential infringement of any proprietary rights of third parties, however, there can be no assurance that such infringements do not exist or may not arise in the future. There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry. Litigation, which could result in substantial cost to and diversion of effort by the Company, may be necessary to enforce patents issued to or licensed by the Company, to protect trade secrets or know-how owned by the Company, to defend the Company against claimed infringement of the rights of others, and to determine the scope and validity of the proprietary rights of others. Adverse determinations in litigation could subject the Company to significant liabilities to third parties or could require the Company to seek licenses from third parties.

Government Regulation

Most of the products manufactured by the Company are devices as defined in the Federal Food, Drug and Cosmetic Act (the Act) and are subject to the regulatory authority of the Food and Drug Administration (FDA), which regulates the manufacture, distribution, related record keeping, labeling and advertising of such devices. The FDA classified medical devices in commercial distribution into one of three classes, Class I, II or III, following the enactment of the Medical Device Amendments to the Act in May 1976 (the Amendments). These classifications are based on the controls necessary to reasonably ensure the safety and efficacy of medical devices. The Company s New Leaf health and fitness products are not classified as medical devices as defined in the Act.

Many Class I devices have been exempted from pre-market notification requirements by the FDA. The same types of controls the FDA has used on devices since the passage of the Act in 1938 can adequately regulate these products. These general controls include provisions related to labeling, producer registration, defect notification, records and reports and good manufacturing practices. The

more comprehensive Quality System Regulation (QSR) has replaced the good manufacturing practice regulation. As noted below, QSRs include implementation of quality assurance programs, written manufacturing specifications and processing procedures, written distribution procedures and record keeping requirements.

Class II devices are products for which the general controls of Class I devices are deemed not sufficient to assure the safety and effectiveness of the device and thus require special controls. Special controls for Class II devices include performance standards, post-market surveillance, patient registries and the use of FDA guidelines. Standards may include both design and performance requirements. Class III devices have the most restrictive controls and require pre-market approval by the FDA. Generally, Class III devices are limited to life-sustaining, life-supporting or implantable devices. All of MedGraphics branded products are Class II devices.

If the Company does not comply with applicable regulatory requirements, including marketing products only for approved uses, it could be subject to fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to grant pre-market clearance or pre-market approval for products, withdrawal of approvals and criminal prosecution. In addition, changes in existing regulations or adoption of new governmental regulations or policies could prevent or delay regulatory approval of the Company s products or result in increased regulatory costs. Furthermore, once clearance or approval is granted, subsequent modifications to the approved product or manufacturing process may require a new round of clearances or approvals that could require substantial additional clinical data and FDA review.

Class II Requirements

Section 510(k) of the Act requires individuals or companies manufacturing medical devices intended for use with humans to file a notice with the FDA at least 90 days before introducing a product not exempted from notification requirements into the marketplace. The notice (a 510(k) Notification) must state the class in which the device is classified and the action taken to comply with performance standards or pre-market approval that may be needed if the device is a Class II or Class III device, respectively. Under Section 510(k), a medical device can be marketed if the FDA determines that the device is substantially equivalent to similar devices marketed prior to May 28, 1976. In the past, Medical Graphics has filed notifications with the FDA of its intent to market its systems pursuant to Section 510(k) of the Amendments, the FDA subsequently cleared these systems for commercial sale and Medical Graphics is now marketing the devices under Section 510(k). The action of the FDA does not, however, constitute FDA approval of Medical Graphics products or pass upon their safety and effectiveness.

In addition to the requirements described above, the Act requires that all medical device manufacturers and distributors register with the FDA annually and provide the FDA with a list of those medical devices that they distribute commercially. The Act also requires that all manufacturers of medical devices comply with labeling requirements and manufacture devices in accordance with QSRs, which require that companies manufacture their products and maintain their documents in a prescribed manner with respect to manufacturing, testing and quality control. In addition, these manufacturers are subject to inspection on a routine basis for compliance with the QSRs. The FDA s Medical Device Reporting regulation requires that companies provide information to the FDA on death or serious injuries alleged to have been associated with the use of their products, as well as product malfunctions that would likely cause or contribute to death or serious injury if the malfunction were to recur. The FDA further requires that certain medical devices not cleared with the FDA for marketing in the United States meet specific requirements before they are exported. The FDA has authority to inspect the Company s facilities to ensure compliance with the Act and regulations thereunder. Failure to comply with these regulations could have a material adverse effect on the Company s business, financial condition and

results of operations. Medical Graphics is registered as a manufacturer with the FDA and successfully passed its most recent FDA audit in September 2004.

Regulation by Foreign Governments

The Company s products are also subject to regulation similar to that of the FDA in various foreign countries. ISO 13485:2003 certification indicates that a company s development and manufacturing processes comply with standards for quality assurance and manufacturing process control. ISO 13485:2003 certification evidences compliance with the requirements that enable a company to affix the CE Mark to its products. The CE Mark denotes conformity with European standards for safety and allows certified devices to be placed on the market in all European Union (EU) countries. Since June 1998, medical devices cannot be sold in EU countries unless they display the CE Mark. Medical Graphics received ISO 13485:2003 certification for its development and manufacturing processes in 1998 and has passed annual surveillance and recertification audits since 1998. Medical Graphics has achieved CE certification for its primary cardiopulmonary testing products. There can be no assurance, however, that Medical Graphics will be able to obtain regulatory approvals or clearances for its products in foreign countries. In addition to compliance with ISO 13485:2003 certification, the Company s products also meet Part I of the Medical Device Requirements for Canada and the Medical Device Directive 93/42/EEC Annex II.

Employees

As of October 31, 2007, the Company had 136 full-time and 4 part-time employees, including 31 in sales, 16 in field service, 11 in marketing, 16 in applications and technical support, 29 in engineering, manufacturing and production, 17 in research, development and quality assurance/regulatory affairs, and 16 engaged in finance and administration. No employees are represented by a collective bargaining agreement and the Company has not experienced any work stoppage. Management believes that relations with its employees are good.

Cautionary Note Regarding Forward-looking Statements

The discussion below contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements by their nature involve substantial risks and uncertainties. The Company s actual results may differ materially depending on a variety of factors, including: (i) our ability to successfully operate our business including our ability to develop, improve, and update our cardiorespiratory diagnostic products and successfully sell these products into existing and new markets, (ii) our ability to achieve constant margins for products and consistent and predictable operating expenses in light of variable revenues from our clinical research customers, (iii) our ability to effectively manufacture and ship products in required quantities to meet customer demands, (iv) our ability to successfully defend ourselves from product liability claims related to our cardiorespiratory diagnostic products and claims associated with our prior cardiac stimulation products, (v) our ability to protect our intellectual property, (vi) our ability to develop and maintain an effective system of internal controls and procedures and disclosure controls and procedures, and (vii) our dependence on third-party vendors.

Additional information with respect to the risks and uncertainties faced by the Company may be found in, and any prior discussion is qualified in its entirety by, the other risk factors that are described from time to time in Angeion s Securities and Exchange Commission reports, including but not limited to this Annual Report on Form 10-K for the year ended October 31, 2007 and subsequently filed reports.

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